REMARKS/ARGUMENTS

This amendment is filed in response to the office action dated April 23, 2003. A petition for a three-month extension of time and appropriate fee accompany this amendment. It appears from the office action that amendments to the drawings, specification and claims filed in response to the PCT written opinion during the international phase of this application were not considered. A copy of applicant's response to the written opinion dated October 22, 2001, is provided for the examiner's reference. To be certain that those amendments are entered, applicant re-submits them here in the present amendment.

Specific comments regarding objections/rejections made in the office action are presented below.

Drawings

In the action, the drawings were objected to for failing to correspond with the specification in the identification of certain reference numerals. In response to the objection that the drawings fail to show reference numeral 2, applicant has amended the specification at page 8, line 7 to change the reference numeral 2 to read "40", as shown in the drawings. The use of the reference numeral 40 to identify the implant generally was originally intended.

Regarding the failure to identify reference numeral 28 in the drawings, applicant has amended the specification at page 8, line 8, to delete the reference numeral 28. The specification states that the tail, if so equipped, may extend along the segment 90 of the obturator. Because the tail is an optional element, it is not shown in the drawings as filed, the identification of reference numeral 28 has been deleted.

The failure to show reference numeral 66 in the drawings has been addressed by amending the specification at page 6, line 17 to refer to the proximally facing edge as reference numeral 63. The edge is shown as element 63 in the drawings and reference to numeral 66 in the specification was a typographical error.

Regarding reference numerals shown in the drawings that are not present in the specification, element 48 has been deleted from FIG. 1 and element 94 has been

deleted from FIG. 8B. Replacement drawing sheets are provided along with annotated sheets explaining the changes made in the drawings. Regarding the omission of elements 52 and 53 from the specification, an amendment has been made at page 5, line 31 to insert a reference to the proximal and distal portions of the implant 52 and 53, respectively. Support for the inserted language defining proximal and distal portions is found at page 3, lines 3-4 of the application.

Specification

In the action, an objection was made to the recitation of "FIG. 13" at page 5, line 6. The specification has been amended to correct a typographical error and now references "FIG. 1" at that passage.

In addition to the objection to the specification mentioned above, applicant has made several additional amendments to the specification to correct typographical errors. These corrections were previously submitted in applicant's response to the written opinion dated October 22, 2001.

At page 4, line 3, after "finished" the word "implant" has been inserted as it was inadvertently omitted from the original text. At page 5, line 25, an omitted word "which" has been inserted after "that". At page 6, line 26, the word "their" has been deleted as it was inadvertently included in the original text.

At page 7, line 11, a typographical error has been corrected to clarify language describing the step in the photochemical etching process as filed. The passage recited: "The sheet is applied to remove the protective coating." The word "light" was omitted from the passage. The corrected sentence now reads, in part, that" "Light is applied to the sheet to remove the protective coating". The step in the photochemical etching process described in that passage is well known to a skilled artisan and the correction of the error is not considered to constitute an introduction of new matter.

Objection to Claim 4

In the action, claim 4 was indicated as defining allowable subject matter, but was objected to as being dependent on a rejected base claim. Claim 4 has now be rewritten in independent form and is considered to be in condition for allowance.

Claim Rejections Under 35 U.S.C. §102

In the action, claims 1, 3, 5, 8-10,13-14 and 18 were rejected as anticipated by U.S. Patent No. 6,425,915 (Khosravi et al.). Claim 1, from which claims 2-13 depend, has been amended to incorporate limitations of claims 6 and 7 an defines rectangular filament with an edge along which is formed at least one barb. Claim 6 has been cancelled. Claim 14 has been amended to include limitations of claim 15, and claim 15 has been cancelled. It is noted that claims 7 and 15 were not found to be anticipated by the Khosravi patent in the action. Amended claims 1 and 14 and all claims dependent thereon should now, likewise, be considered not to be anticipated by Khosravi.

Claims 1 and 14

Claim 1 now defines an implant device comprising a flexible helical spring formed from a filament having a rectangular cross-sectional profile, having a plurality of coils, each having an edge along which is formed at least one barb that engages surrounding tissue. Khosravi does not disclose a helical spring implant with at least one barb along the edge of a coil. Claim 14 now defines a method of forming an implant device comprising forming a ribbon having at least one projecting barb shape on an edge of the ribbon and wrapping the ribbon into a helical coil shape. As mentioned above, Khosravi does not show forming barb shapes on the edge of a helical ribbon.

Khosravi shows a helical stent wrapped from an element that is a rectangular lattice. Integrally formed in the lattice structure are barbs that project outward when the element is wrapped to form the stent. The barbs are part of the lattice work in the center area of the element that is wound into the coils of the stent (as seen in FIG 5A of Khosravi), not on the edge of the coils as defined in the applicant's claims. Rather than teaching placing barbs on the edge of the coils, Khosravi teaches that the coils of the

stent should be configured to be adjacent to and preferably overlap each (as shown in the figures and explained at col. 6, lns. 47-53 of Khosravi). Barbs on the edges of the cols of Khosravi would interfere with the intended operation of the device as overlapping edges of the coils slip past each other during the unwinding that occurs during expansion. Accordingly Khosravi should not be considered to anticipate claims 1 and 14 as amended nor the claims dependent on claims 1 and 14.

Claim 8

The rejection of claim 8 as anticipated by Khosravi is traversed. Claim 8 has been rewritten in independent form and is presented for reconsideration. Applicant's claim 8 defines that the spring is formed from a plurality of materials, each having different moduli of elasticity. The Khosravi patent discloses only stents that are made from a single material.

The passage of the Khosravi patent cited in the action (col. 6, lines 17-22) as describing a stent made from multiple materials appears to have been misunderstood by the examiner. The passage states that "Stent 10 comprises a thin (about a 1-5 mils) band of a biocompatible material, such as a thermal shape-memory polymer or metal, super-elastic material such as a nickel-titanium alloy or other biocompatible elastic material such as a stainless steel, tantalum, platinum or tungsten alloy." (emphasis supplied.) The passage cited discloses that the stent is formed from a single material, but several alternative choices for that single material may be suitable. The passage does not disclose that a single helical stent may be formed from multiple materials, as defined in claim 8.

Claim Rejections - 35 U.S.C. §103

In the action, claims 2, 6-7, 12-13 and 15-17 were rejected as obvious based on Khosravi and the Pinchuk patent. As mentioned above, claim 1 has been amended to include limitations of claim 6 and 7 and claim 14 has been amended to include limitations of claim 15. Applicant traverses the obviousness rejection for the reasons presented below and considers amended claims 1 and 14 and all claims dependent thereon to be patentable.

Amended claim 1 defines a flexible helical spring formed from a filament having a rectangular cross-sectional profile, having a plurality of coils, each having an edge along which is formed at least one barb. Khosravi does not disclose an implant with coils having barbs formed along edges of the coils. Rather, Khosravi discloses barbs formed in the center of each coil winding. The barbs are formed within the lattice pattern created throughout the center of the element that is later wrapped to become a coil in Khosravi. As explained in the present application, forming the barbs along one edge of the element that is later wound to become a spring coil facilitates manufacturing and simplifies directing the barbs proximally from the edge of each coil in a manner that will serve to resist migration from tissue when it is implanted. It is desirable to have the barbs directed in a proximally facing direction because the implant inserted into tissue in a distal direction will most likely be susceptible to withdrawal movement back out along the pathway in which it was inserted (i.e., proximally). If, as suggested in the action, it would have been obvious to one having ordinary skill in the art to place the barb on the proximal facing edge of the coil and such placement is a matter of design choice, then why would Khosravi not have obtained the benefits in resisting migration and manufacturability described above by placing the barbs of his disclosed implant on the proximal facing edge of each coil? Applicant's position is that it would not have been obvious to place barbs on the edge of a coil as is now defined in the claims. Furthermore, the failure of the prior art to recognize the benefits of the arrangement of barbs on the edge of the coils suggests the non-obviousness of the concept now claimed.

The Pinchuk patent adds nothing to the propriety of the obviousness rejection, as it merely discloses a helical coil stent with no barbs whatsoever. The primary reference, Khosravi also shows a helical coil implant. Because Pinchuk provides no disclosure or motivation to place barbs on the proximal edge of the implant coil, its combination with the Khosravi patent does not render the claimed arrangement as obvious. Accordingly, claim 1 should not be considered to be obvious by the combination of Khosravi and Pinchuk.

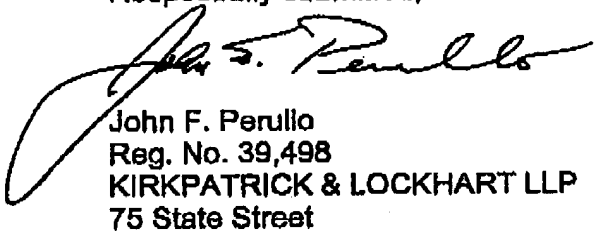
Claim 14, amended to include limitations of claim 15, defines a method of forming a tissue implant device comprising forming a ribbon having at least one projecting barb shape on the edge of a ribbon. As discussed above, neither Khosravi nor Pinchuk disclose or suggest placing a barb on the edge of a helical winding. Accordingly, amended claim 14 and claims 16-18 that depend from it should be considered patentable over the combination of those references.

Claim 11 was rejected based on the combination of Khosravi and U.S. patent 6,053,943 (Edwin et al.). Claim 11 is dependent on claim 1 and is considered to be patentable for all of the same reasons discussed above in connection with claim 1.

New claims 19-24 have been added and are presented for consideration. It is noted that these new claims were originally presented in the response to the PCT Written Opinion during the international phase of this application.

Based on the foregoing, all claims are considered to be patentable and in condition for allowance and such action is earnestly solicited.

Respectfully submitted,



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